

This application contains the following items: <i>(Check all that apply)</i>		
1.	Index	
2.	Labeling <i>(check one)</i> <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling	
3.	Summary (21 CFR 314.50 (c))	
4.	Chemistry section	
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)	
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)	
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)	
5.	Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)	
6.	Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
7.	Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))	
8.	Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
9.	Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	
10.	Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)	
11.	Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	
12.	Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)	
13.	Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))	
14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))	
15.	Establishment description (21 CFR Part 600, if applicable)	
16.	Debarment certification (FD&C Act 306 (k)(1))	
17.	Field copy certification (21 CFR 314.50 (l)(3))	
18.	User Fee Cover Sheet (Form FDA 3397)	
19.	Financial Information (21 CFR Part 54)	
20.	OTHER <i>(Specify)</i>	
CERTIFICATION		
<p>I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:</p> <ol style="list-style-type: none"> 1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820. 2. Biological establishment standards in 21 CFR Part 600. 3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809. 4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202. 5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12. 6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81. 7. Local, state and Federal environmental impact laws. <p>If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.</p> <p>The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.</p> <p>Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.</p>		
SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT		DATE
TYPED NAME AND TITLE		
ADDRESS <i>(Street, City, State, and ZIP Code)</i>		Telephone Number
<p>Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (HFD-143) Central Document Room 5901-B Ammendale Road Beltsville, MD 207052-1266</p> </div> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research (HFM-99) 1401 Rockville Pike Rockville, MD 20852-1448</p> </div> <div style="width: 45%;"> <p>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</p> </div> </div>		